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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,435	12/12/2006	Daisuke Shoji	P30635	8794
7055                      7590                      10/30/2008 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER				
WANG, CHUN CHENG				
ART UNIT		PAPER NUMBER		
1796				
NOTIFICATION DATE		DELIVERY MODE		
10/30/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

# Office Action Summary

**Application No.**

10/599,435

**Applicant(s)**

SHOJI ET AL.

**Examiner**

Chun-Cheng Wang

**Art Unit**

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/309)  
Paper No(s)/Mail Date 01/11/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. JP 2004-100765, filed on 03/30/2004.

### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities: Replace "In the production of a porous body..." to "A method for controlling the average pore diameter of a porous body...". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang ("Preparation of a porous hydroxyapatite/collagen nanocomposite using glutaraldehyde as a crosslinkage agent", Journal of Materials Science Letters 20, 2001, 1199 – 1201) in view of Lee et al. ("Characterization of UV-irradiated Dense/porous Collagen Membranes: Morphology, Enzymatic, Degradation, and Mechanical Properties", Yonsei Medical Journal, Vol. 42, No. 2, pp. 172-179, 2001).

Chang discloses a homogeneous suspension of  $\text{Ca(OH)}_2$  dispersed in  $\text{H}_2\text{O}$  and  $\text{H}_3\text{PO}_4$  aqueous solution with collagen was gradually added into a reaction vessel through tube pumps, then an aqueous solution of glutaraldehyde, i.e. crosslinking agent, was slowly dropped into the slurry solution. The hydroxyapatite/collagen precipitates obtained were dried in a freeze dryer at  $-30^\circ\text{C}$  under vacuum (second and third paragraph, page 1199).

Chang is silent on using temperature in freezing step to control pore diameter.

Lee et al. disclose UV or glutaraldehyde (GA) treated collagen-based membranous materials were fabricated by freeze-drying processes. As the freezing temperature decreased to  $-196^\circ\text{C}$ , the resultant mean pore sizes also decreased; optimal pore size was obtained at a freezing temperature of  $-70^\circ\text{C}$  (Abstract). Size and morphology of the pores in collagen-based biomaterial normally make a great contribution to its ability to facilitate tissue regeneration. A three-dimensionally interconnected porous structure in a collagen-based biomaterial provides vascularization and cellular colonization when in contact with living tissues. The size and morphology of the pores are recognized to be dependent upon the freezing temperature of the mixture before lyophilization. The optimal pore size ranges between 50 and 150 m, and that

pores of this size can provide appropriate space for cellular infiltration and proliferation. The optimal pore size was obtained when the collagen precipitate was freeze-dried at  $-70^{\circ}\text{C}$  (left column, pp 177).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to utilize the teaching from Lee et al., using the freezing temperature to control pore diameter, and combine with the teachings from Chang to prepare porous apatite/collagen composite materials.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun-Cheng Wang whose telephone number is (571)270-5459. The examiner can normally be reached on Monday to Friday w/alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ling-Siu Choi/  
Primary Examiner, Art Unit 1796

Chun-Cheng Wang  
Examiner  
Art Unit 1796

/CCW/